

Application for United States Letters Patent
for

Portable Patient Data Processing System and Method

by

Edward R. Rensimer

Jacqueline P. Tomsovic

Pamela A. Wright

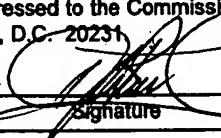
Express Mail Mailing Label: RB 669 448 802 US

Date of Deposit: August 24, 1994

Pursuant to 37 C.F.R. § 1.10, I certify that I am personally depositing this paper or fee with the United States Postal Service's "Express Mail Post Office to Addressee" service on the above date in a sealed envelope (a) having the above numbered Express Mail label and sufficient postage affixed and (b) addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Luis Rivera

Printed name



Signature

ARNOLD, WHITE & DURKEE
750 BERING DRIVE
HOUSTON, TEXAS 77057

Table of Contents

1. REFERENCES	1
2. BACKGROUND OF THE INVENTION	1
3. SUMMARY OF THE INVENTION.....	2
4. BRIEF DESCRIPTION OF DRAWINGS	3
5. DETAILED DESCRIPTION OF A SPECIFIC EMBODIMENT.....	3
5.1 Apparatus.....	4
5.2 Method.....	5
5.3 Clinical Status Code Components of a Patient.....	5
5.4 Steps for Determining a Patient's Clinical Status Code.....	7
5.5 Advantages of the Invention.....	11
6. CLAIMS	13
7. ABSTRACT	19

1 **1. REFERENCES**

2
3 Certain aspects of the instant invention are similar to those disclosed in co-pending U.S. Patent
4 Application No. 08/259,338 filed May 13, 1994, entitled "Portable Patient Data Processing System and
5 Method" by Edward R. Rensimer. Application 08/259,338 is a continuation of U.S. Patent Application
6 07/877,868, filed May 4, 1992 and commonly owned with the instant application. Both applications are
7 incorporated here, in their entirety, by reference.

8
9 Additionally, certain terminology and definitions described in the 1994 edition of the Physicians'
10 Current Procedural Terminology manual (referred to as CPT or CPT94) are incorporated herein by
11 reference. The CPT manual provides a standard classification of medical procedures and is well known
12 to those of ordinary skill in the field.

13
14 **2. BACKGROUND OF THE INVENTION**

15
16 The invention relates to a hand-held physician's computer and database system configured to collect,
17 store, and report historical patient-care information at the site of patient service. The system and method
18 permits a physician, or other care-provider, to record not only patient status information but, importantly,
19 other patient-treatment information as well

20
21 Many prior patient data systems focused more on data about current patient status than on
22 historical data about the care given to the patient. Such data conveyed comparatively little or no
23 information about the physician and other medical-staff resources that were previously utilized in caring
24 for the patient. One of the most common methods of recording patient care information is the so-called
25 superbill. The superbill is a multipart paper form that is preprinted with numerous broad categories of
26 standard services. The physician checks off one or more of the categories of care, and might make
27 handwritten notes about the specific diagnosis and/or services provided (e.g., otitis media or amoxicillin).

1 The superbill has several drawbacks, including a comparative lack of precision or "granularity" because
2 of the limited space on the preprinted paper form.

3

4 **3. SUMMARY OF THE INVENTION**

5

6 A system and method for building more complete patient history data permits physicians and
7 other medical staff personnel to record, accurately and precisely, the treatment or care given in a
8 particular patient encounter. One benefit of the invention is the generation of an objective measure of a
9 physician's rendered level of care, as described by a clinical status code, in a novel modification of a
10 standard classification system. Data elements used in the determination of the clinical status code include
11 a level of history of the patient, a level of examination of the patient, a decision-making process of the
12 physician treating the patient, and a "time influence factor."

13

14 Other attendant benefits of the invention include: (1) enhancement of the quantity and quality of
15 care information for a particular patient, allowing future care decisions for that patient to be based on a
16 more complete medical history; (2) enhanced care information can be used in outcome studies to track the
17 efficacy of specific treatment protocols; (3) historical data about physician workload can be easily
18 gathered which, in turn, can contribute to a better understanding and allocation of the professional
19 resources actually used in a given practice during a particular period of time; (4) generated clinical status
20 codes can be used in requesting payment for medical services from insurance companies or other payors;
21 (5) archiving of patient information in a manner which allows reconstruction of the qualitative aspects of
22 provided medical services; (6) real-time sharing and communication of clinical data between physicians;
23 (7) standardization of nomenclature used by groups of physicians in caring for patients; (8) automatic and
24 clean data capture and storage of medical record data that would otherwise be done manually, and (9) the
25 ability to record, transfer, and save medical care data from a portable system to a larger stationary
26 information or database system. Considerable physician and staff time are saved, and the precision and
27 accuracy of patient treatment history are significantly enhanced, by recording these activities

1 contemporaneously with the service rendered.

2

3 **4. BRIEF DESCRIPTION OF DRAWINGS**

4

5 Figure 1 is a block diagram of a portable patient data processing system in accordance with the
6 invention.

7

8 Figure 2 is a high level flow diagram of a method in accordance with the invention.

9

10 Figure 3A and 3B are two screen views of an exemplary "patient diagnosis" prompt window in
11 accordance with the invention.

12

13 Figure 4 is a screen view of an exemplary "patient service type" prompt window in accordance
14 with the invention.

15

16 Figure 5 is a screen view of an exemplary "key element level" select prompt window in
17 accordance with the invention.

18

19 Figure 6 is an exemplary logic table describing a means of determining a clinical status code for a
20 service type of "Office (outpatient visit) Services". See also microfiche Appendix A.

21

22 Figure 7 is a flow diagram for Figure 6.

23

24 **5. DETAILED DESCRIPTION OF A SPECIFIC EMBODIMENT**

25

26 One illustrative embodiment of the invention is described below as it might be implemented using a
27 hand-held general purpose computer. In the interest of clarity, not all features of an actual implementation

1 are described in this specification. It will of course be appreciated that in the development of any such actual
2 implementation (as in any development project), numerous implementation-specific decisions must be made
3 to achieve the developers' specific goals and subgoals, such as compliance with system- and business-related
4 constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such
5 a development effort might be complex and time-consuming, but would nevertheless be a routine
6 undertaking of device engineering for those of ordinary skill having the benefit of this disclosure.

7

8 Microfiche Appendix A contains a listing of clinical status code selection logic tables in accordance
9 with the invention. Microfiche Appendix B contains source code listings, in the 'C' programming language,
10 that embody one implementation of the inventive method. Microfiche Appendix C contains documentation
11 for certain aspects of one embodiment of the invention (see source code listings, Appendix B). Microfiche
12 appendixes A, B, and C contain a total of 7 sheets and 571 frames.

13

14 A portion of the disclosure of this patent document contains material which is subject to copyright
15 protection. The copyright owner has no objection to the facsimile reproduction by anyone of the patent
16 disclosure, as it appears in the Patent and Trademark Office patent files or records, but otherwise reserves all
17 copyright and similar rights whatsoever.

18

19 5.1 Apparatus

20

21 Figure 1 shows two personal computers, depicting an overall representation of a system in
22 accordance with the present invention. The first is a relatively stationery desktop personal computer
23 comprising a CPU chassis 100, to which is coupled a keyboard 110 and a CRT display 120. The desktop
24 personal computer is, in the preferred embodiment, an IBM compatible personal computer. Figure 1
25 further shows personal computer 130 of the hand-held type, which is, in the preferred embodiment, of a
26 bivalve type (e.g., Hewlett-Packard 100 and 200 LX series of computers, although the present invention is
27 not limited to these specific computing hardware types). That is, it opens in a clamshell manner to reveal

1 therein a screen and keyboard, not separately referenced. The first and second personal computers are
2 disconnectedly coupled by a link 140 comprising, for example, a plurality of separate wires in a bundle or
3 alternatively an optical or radio link of the kind well-known in the art. (The HP 100LX and HP 200LX
4 hand-held computers have infrared optical links built-in.). It is irrelevant for purposes of the present
5 invention that the link 140 be a parallel or serial link; either one is contemplated.

6

7 In the preferred embodiment, the hand-held personal computer 130 is designed to be detached
8 from the desktop personal computer and taken with the physician, or other medical care-taker, on his
9 clinical rounds to enter and extract information. When the physician returns from his clinical activities,
10 the hand-held personal computer 130 may be rejoined to the desktop personal computer by means of the
11 link 140 to thereby transfer information there between.

12

13 5.2 Method

14

15 Figure 2 shows a high-level view of a method (executed by a device such as hand-held computer
16 130 and operated by medical professional staff) of generating a signal quantifying a physician
17 intervention status of a patient. The signal is referred to for convenience as a "clinical status code." It
18 will be apparent that the device can be intuitively operated by multiple medical staff members in
19 sequence, e.g., by a nurse, a physician, an office administrator, a receptionist, and the like, to the extent
20 consistent with proper medical practice. Individual steps, outlined in Figure 2, are discussed in more
21 detail below.

22

23 5.3 Clinical Status Code Components of a Patient

24

25 The clinical status code is a function of a number of patient-related items. Three such items are
26 referred to as "key elements" of the clinical status code, namely (1) a level of medical history of the
27 patient, (2) a level of physical examination of the patient, and (3) a medical decision-making process of

1 the physician treating the patient. A fourth important patient-related factor is a "time influence factor."

2

3 The level of history and level of examination are standard indicators, defined in the CPT manual,
4 of the intensity of service rendered by medical personnel in obtaining patient history and in examining the
5 patient. Four standard levels are associated in each of the level of history and level of examination.
6 These levels are (1) problem-focused; (2) expanded problem-focused; (3) detailed; and (4)
7 comprehensive.

8

9 The decision-making process of a physician treating the patient refers to CPT-standard indicators
10 of three different decision components: (1) risk of complications and/or morbidity or mortality, referred
11 to simply as "risk;" (2) the amount and/or complexity of data to be reviewed, referred to simply as
12 "complexity;" and (3) the number of diagnoses or management options considered by the physician,
13 referred to simply as "diagnoses." Each of the three decision components has four possible levels:

14

Decision Component	Level
1. Risk	Minimal
	Low
	Moderate
	High
2. Complexity	Minimal or None
	Limited
	Moderate
	Extensive
3. Diagnoses	Minimal
	Limited
	Multiple
	Extensive

15

16

17 The time influence factor refers to an adjustment to the CPT-standard amount of time associated
18 with a particular CPT clinical status code. The adjustment takes into account the physician's actual work

1 time associated with a patient encounter, as a function of an amount of unit floor time (or face-to-face
2 time) spent by the physician in connection with the patient encounter, or of an amount of time spent by
3 the physician in counseling or coordination of care for the patient.

4

5 Consider a hypothetical example of a time influence factor: A clinical status code of "1-1-1"
6 represents a new-patient encounter, i.e., an encounter at the lowest level of history, examination, and
7 decision making process for a new patient, is associated with a CPT-standard amount of time of 10
8 minutes. If the encounter is prolonged to 20 minutes because of, say, an extended face-to-face discussion
9 between the patient and physician (or with the patient's spouse, parent, or other responsible party, e.g., a
10 person holding a medical power of attorney), a time influence factor is entered to reflect the extra 10
11 minutes spent by the physician in the patient encounter and may modify the clinical status code generated
12 in accordance with the invention.

13

14 5.4 Steps for Determining a Patient's Clinical Status Code

15

16 The method steps shown in Figure 2 are as follows:

17

18 200 Start of a method in accordance with the invention.

19

20 205 A data store (not shown) is consulted to determine whether a diagnosis already exists for the
21 patient in question.

22

23 210 If a diagnosis does not exist, the user is prompted to select a diagnosis; a diagnosis code
24 representing the selected diagnosis for the patient is stored in the data store. Figure 3 shows
25 views of two diagnosis prompt windows. Figure 3A is a generic Diagnosis prompt window while
26 Figure 3B shows a partial (exemplary) list of possible diagnoses. If the staff member determines
27 that the available diagnoses presented for selection not adequately describe the diagnosis for the

1 patient, the staff member may enter an additional diagnosis by selecting a conventional "Add
2 New Diagnosis" function. The staff member is then given the option of placing the newly added
3 diagnosis into a master diagnosis table. Staff members can then select the newly added diagnosis
4 during the normal course of clinical evaluations.

5

6 215 The staff member is prompted to select a service type, referred to as a selected service type, as
7 shown in Figure 4. The CPT-standard service types are: (a) outpatient services, (b) hospital
8 observation services, (c) hospital inpatient services, (d) hospital discharge services, (e) outpatient
9 consultations, (f) inpatient consultations, (g) inpatient follow-up consultations, (h) confirmatory
10 consultations, (i) emergency services, (j) critical care visits, (k) neonatal intensive care, (l)
11 nursing facility services, (m) domiciliary, rest home, or custodial care, (n) home services, (o)
12 prolonged services, (p) case management team services, (q) case management phone services, (r)
13 care plan oversight services, (s) preventive medicine services, (t) preventive medicine individual
14 counseling, (u) preventive medicine group counseling, and (v) newborn care.

15

16 220 A series of questions are displayed to the staff member. The questions are designed and arranged
17 for enhanced human-factors ("ergonomic") effectiveness to obtain quickly certain information
18 needed for determining the clinical status code. The specific questions asked are determined in
19 part by the selected service type. The answer to any given question may influence which
20 questions are subsequently asked. A specific set of questions, primarily of the yes-no variety, are
21 reproduced in the source-code listings of microfiche Appendix B of this application; a specific
22 example is discussed in connection with Figures 6 and 7 below.

23

24 225 The staff member is prompted to select, for each respective key element (see discussion above), a
25 level for the key element. An exemplary key element level screen prompt is shown in Figure 5.

26

27 230 From the selected levels for the decision-making process, a specific level for the type of medical

1 decision making (straightforward, low complexity, moderate complexity, high complexity) is
2 computed in accordance with the table on page 13 of CPT94. It will be understood, of course,
3 that the level of medical decision-making can be computed later as part of the ultimate
4 determination of the clinical status code.

5

6 **235** A test is made to determine whether the selected service type falls within an exception category.
7 Exception categories include (a) hospital discharge services, (b) observation discharge services,
8 (c) critical care, (d) care plan oversight services, (e) case management team services, (f) prolonged
9 services, (g) neonatal intensive care, (h) case management phone services, (i) preventive
10 medicine services, (j) emergency advanced life support services, and (k) newborn care.

11

12 **240** If the selected service type does not fall within an exception category, then the clinical status code
13 is determined as a function of one or more of (1) the selected service type; (2) the selected levels,
14 including the computed level of medical decision making; and (3) if the physician entered an
15 amount of service time, the amount of service time. Determination of a clinical status code is
16 made in accordance with the logic tables shown in microfiche Appendix A.

17

18 **245** If the selected service type is associated with a time influence factor, then the physician is
19 prompted to enter an amount of service time.

20

21 **250** Determination of an "exception" clinical status code, as set forth above, is made in accordance
22 with the logic tables given in microfiche Appendix A.

23

24 Table 1 shows a set of service-type guidelines for using the key elements and the physician's time
25 influence factor in selecting a clinical status code. It will be appreciated by those of ordinary skill having
26 the benefit of this disclosure that Table 1 provides a novel and concise alternative encoding of the CPT
27 rules set forth on pages 13-14 of CPT94. Table 1 is one of the tables comprising microfiche Appendix A.

Table 1. Service type Guidelines

Definitions: N = New patient, E = Established patient

upper area: History, Exam, Medical Decision key elements

50 % question: amount of time spent in face-to-face contact with patient

Must meet or exceed all of the key components of history, exam, medical decision-making (3/3)	Time	Must meet two of the three key components of history, exam, and medical decision-making (2/3)
Office:(outpatient) (N)	Factor	Office:(outpatient) (E)
Hospital observation services (N/E)		
Initial hospital care (N/E)	Factor	Subsequent Hospital Care
Office Consult (outpatient)(N/E)	Factor	
Initial Inpatient Consult (N/E)	Factor	Follow-up Inpatient Consultation(E)
Confirmatory Consult (N/E)		No 50% question
Emergency Department		
Critical care	Factor	No 50% question(30 minute increments)
Neonatal Intensive Care		No 50% question
Comprehensive Nursing Facility (N/E)	Factor	Subsequent Nursing facility care (N/E)
Domiciliary Care (rest home): (N)		Domiciliary care :(E)
Home Care: (N)		Homecare: (E)
Prolonged Services	Factor	No 50% question
Physician Standby	Factor	No 50% question
Case Management	Factor	No 50% question
Care Plan Oversight Services	Factor	No 50% question
Preventive Medicine		No 50% question
Counseling	Factor	No 50% question
Newborn Care		No 50% question
Rest Home (N)		Rest Home (E)
">50% unit/floor-counseling/coordination?" Service types: office/outpatient visit; office consultations		
">50% unit/floor-counseling/coordination?" Service types: nursing, assessment and subsequent, initial consult, inpatient hospital care, follow-up consultation		
WHENEVER TIME IS AN ELEMENT OF DECISION-MAKING WE SHOULD ASK THE QUESTION OF 50% except for <u>Critical Care</u> , <u>Preventive medicine</u> , <u>Prolonged services</u> , <u>Physician Standby</u> , <u>Case Management</u> , <u>Care Plan Oversight Services</u> , and <u>Counseling</u> . Time then becomes the controlling factor, such that time can adjust the CPT upward, should always compare which gives the greater code with key elements or key elements using time. Selection of the code is then based on which of the two gives the higher coding element.		

1

2

3 Figure 6 is an example of a decision table for determining a clinical status code for a particular

4 type of service, i.e., Office (outpatient visits) Services. The decision table of Figure 6 is shown in flow-

1 chart form in Figure 7.

2

3 **5.5 Advantages of the Invention**

4

5 The system and method of the invention permits physicians and other medical staff members to
6 conveniently record patient-treatment data. The system and method may be used for developing
7 historical data about physician workload in an inpatient or outpatient setting. Such historical data
8 contributes to a better understanding of the professional resources actually used in a given practice during
9 a particular period of time. That understanding in turn permits improved resource allocation, e.g., better
10 scheduling of work for specific physicians (and other medical professionals) in a hospital or a group or
11 solo practice to accommodate anticipated patient-care workload. Understanding the type of work most
12 commonly done allows improved decisions on the type of professional manpower needed.

13

14 The inventive system and method permits a physician to record, accurately and precisely, patient
15 care information in a manner that requires considerably less physician and staff time. As a result, more
16 physician time can be spent actually rendering patient care. In addition, the quantity and quality of
17 historical care information for a particular patient is enhanced, meaning that future care decisions for that
18 patient can be based on a more complete medical history database. Moreover, such enhanced care
19 information can be put to use in outcome studies to track the efficacy of specific treatment protocols. In
20 many ways, including how specific diagnostic/treatment approaches can change the quantity and quality
21 of medical professional man-hours.

22

23 It will also be understood by those of ordinary skill that the clinical status codes generated as
24 described above are the same as those used in requesting payment from insurance companies.
25 Considerable physician and staff time are saved, and precision and accuracy are significantly enhanced,
26 by generating these clinical status codes automatically (at the point of service by the care-provider
27 without any intermediary steps) from information recorded simultaneously with the provision of services.

1

2



3

4 It will be appreciated by those of ordinary skill having the benefit of this disclosure that numerous
5 variations from the foregoing illustration will be possible without departing from the inventive concept
6 described herein. Accordingly, it is the claims set forth below, and not merely the foregoing illustration,
7 which are intended to define the exclusive rights claimed in this application program.